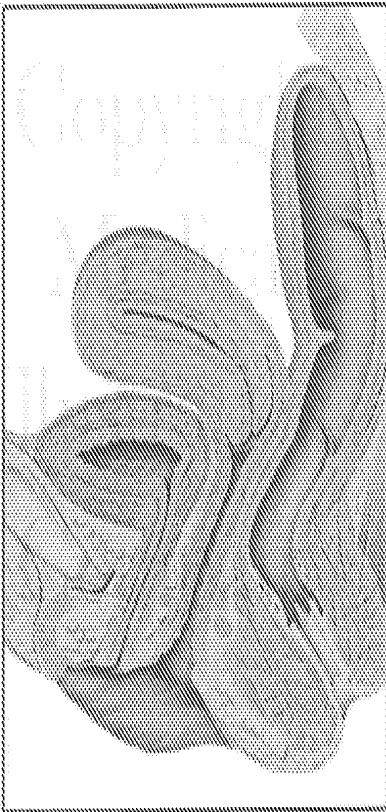


APPENDIX

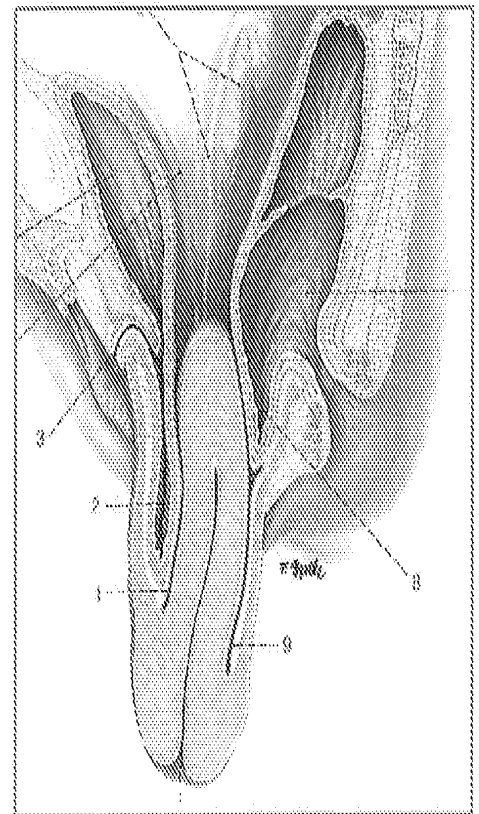
US patent application 10/523,144

Device structural and functional considerations

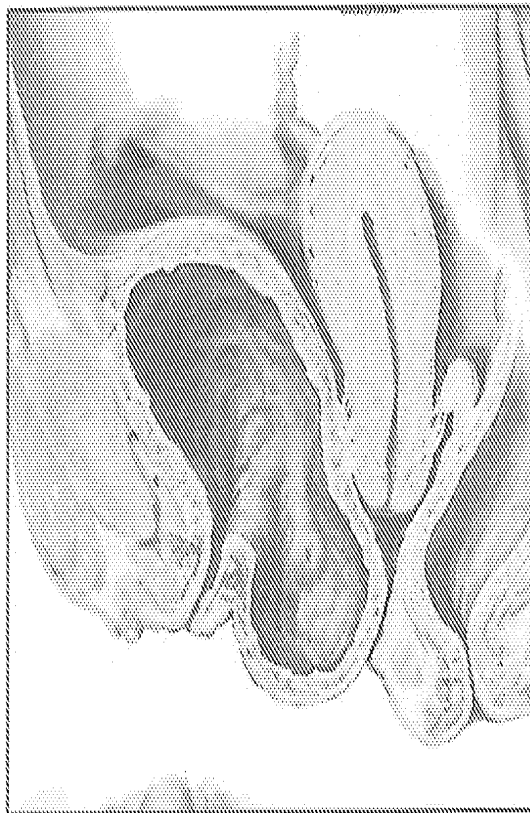
Normal
anatomy



Total Prolapse

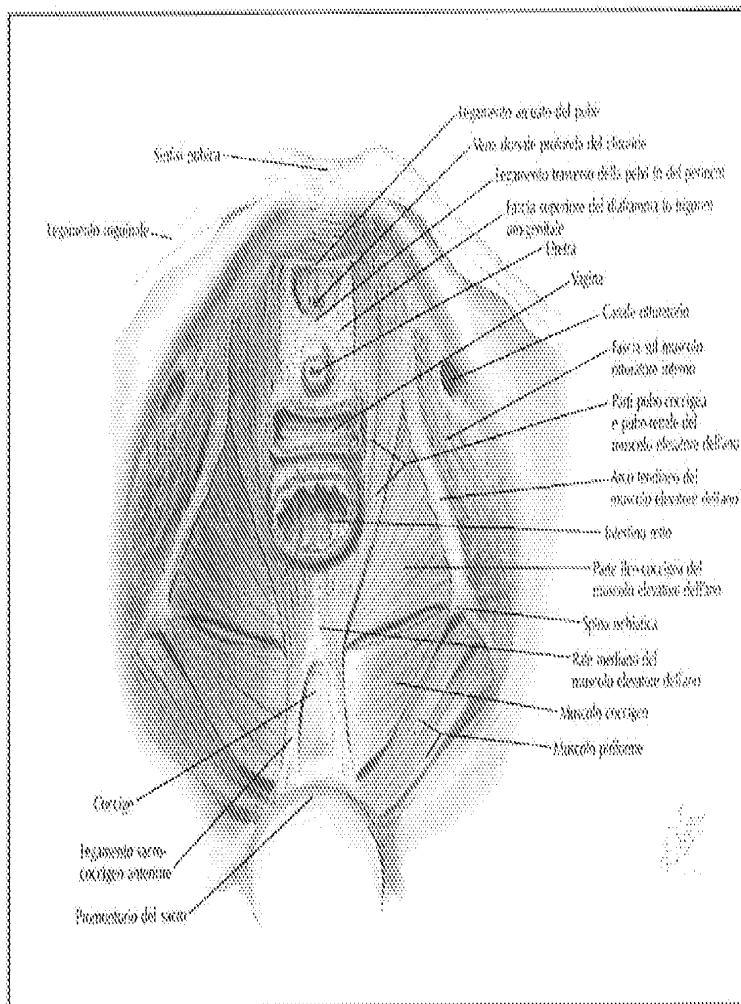


Anterior Prolapse

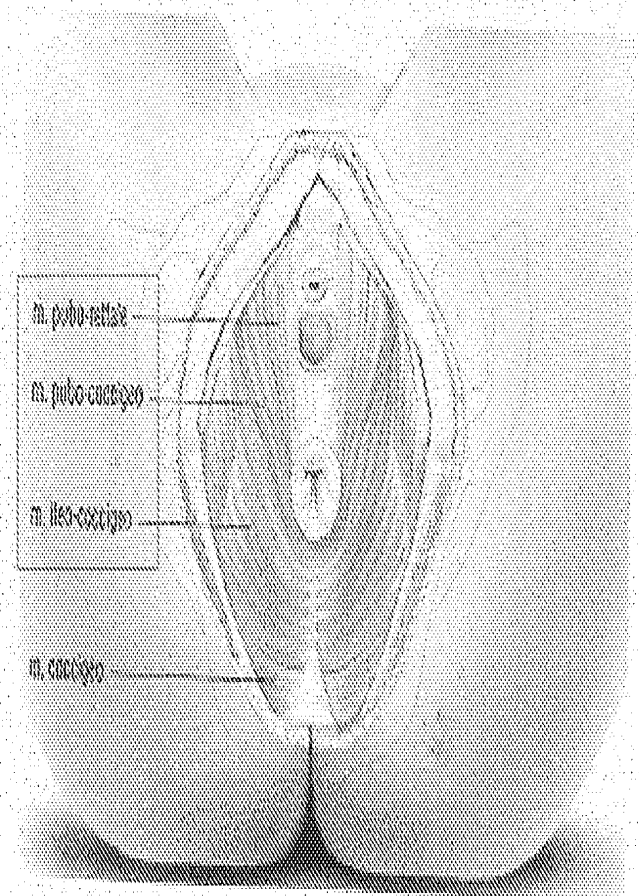


Pelvic Floor Muscles

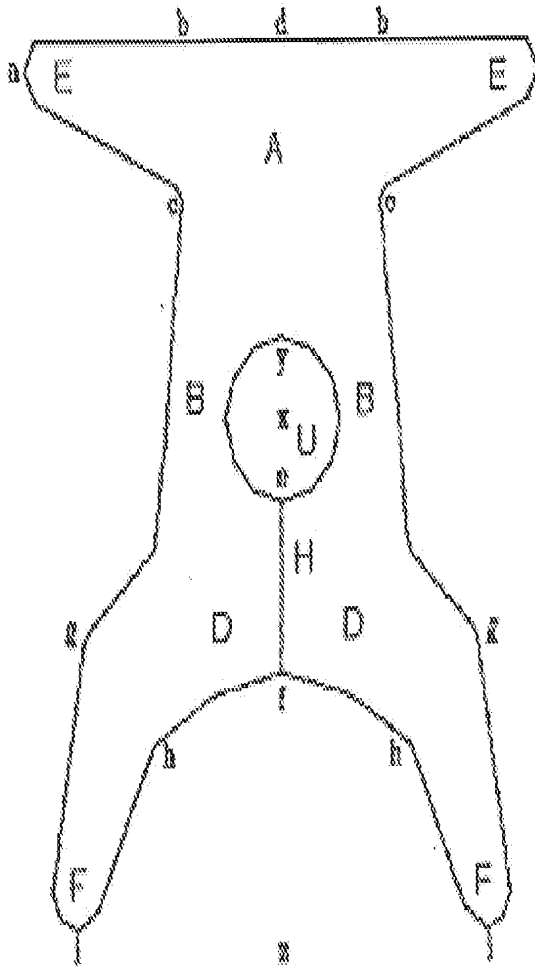
Intra abdominal view



Perineal view



The instant device structure



31. A flat implantable device made of material with a reticular or laminar structure for supporting the female pelvic organs, having a central body with a trapezoid shape with four arms, in which may be distinguished:

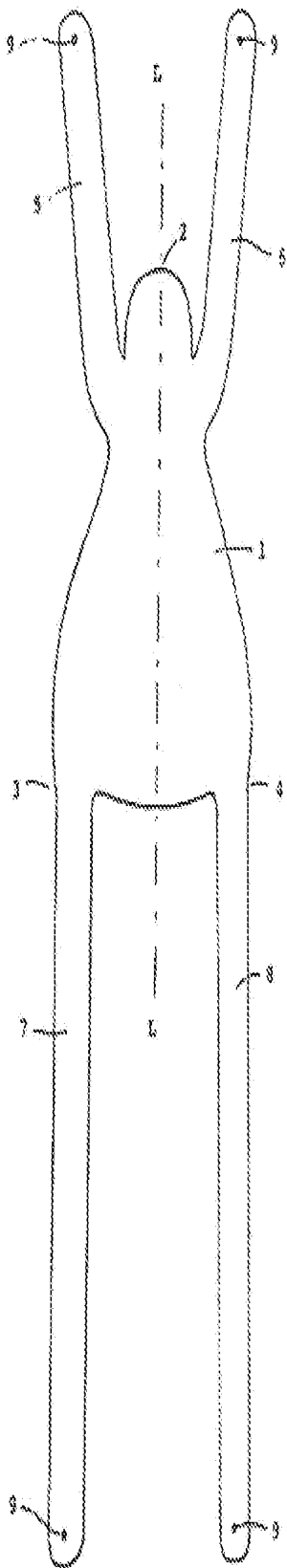
a front portion (A) corresponding to the smaller base of the trapezium, from the ends of which branch off two arms (E);

a central portion (B) corresponding to the central part of the trapezium;

a rear portion (D) corresponding to the larger base of the trapezium, from the ends of which branch off two arms (F) diverging from each other and parallel to the sides of the trapezium;

characterised in that the said two arms (E) branch off from the front portion (A) in opposite directions and are coaxial with each other and parallel to said smaller base; and the said central portion (B) has a central hole (U) from which starts a cleft (H).

Landgrebe device structure



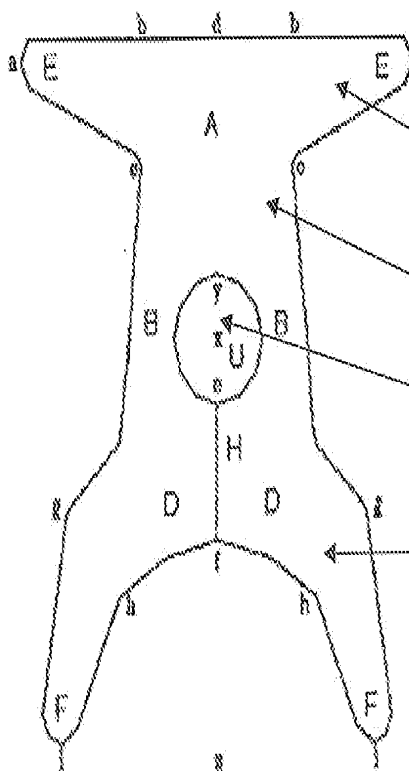
A base 1 is triangle-like to elongated oval in shape and has a longitudinal axis L-L. In the embodiment example, the base 1 rather resembles a triangle with the corners 2, 3 and 4, the corner 2 (through which the longitudinal axis L-L of the base 1 runs) being rounded. The area of the base is about 30-50 cm².

From the base 1, close to the corner 2 but at a distance from this, a first projection 5 which is bridle-like in construction starts. The first projection 5 runs on the left-hand side of the longitudinal axis L-L at a sharp angle with respect to the longitudinal axis L-L, which is less than 20° in the embodiment example. Another first projection 6 which has the same form as the first projection 5 is arranged in mirror symmetry to the longitudinal axis L-L.

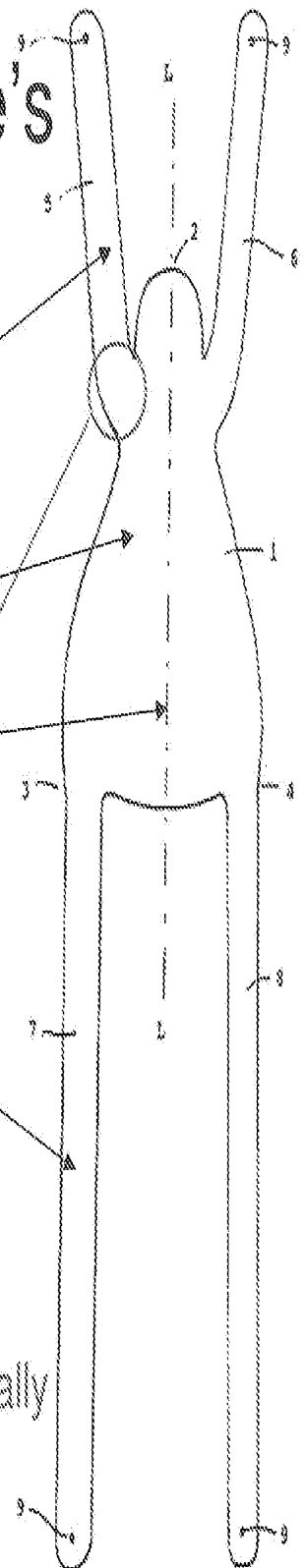
From the corner 3 of the base 1, a second projection 7 which runs on the left-hand side of the longitudinal axis L-L and essentially parallel to this starts. The second projection 7 is thus generally directed in the opposite direction to the first projection 5, i.e. while the first projection 5 in Figure 1 extends (at an angle) upwards, the second projection 7 runs downwards. Like the first projection 5, the second projection 7 could also form an angle to the longitudinal axis L-L of the base 1 which differs from 0°. From the corner 4 of the base 1, another second projection 8 which runs in mirror image to the second projection 7 in respect of the longitudinal axis L-L starts. The two second projections 7 and 8 have the same dimensions and are longer than the two first projections 5 and 6.

See column 2 lines 30-59

Structural configuration of instant device claims vs Landgrebe's

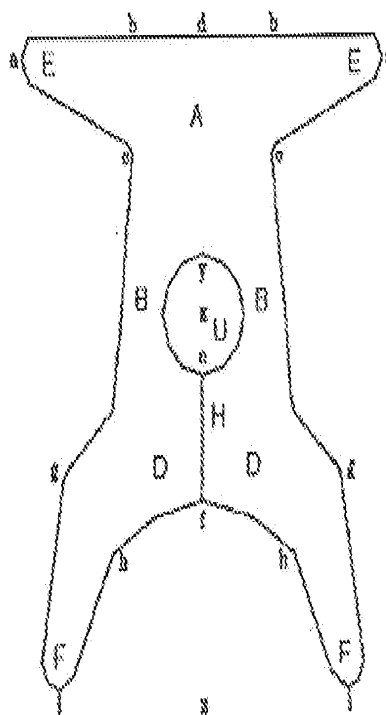


Nicita's device		Landgrebe's device
Wide apart (coaxial) horizontally stretched	ARMS	raised aloft
trapezoidal	CENTRAL PORTION	triangular
present	CENTRAL HOLE	absent
short and wide apart slightly folded	LEGS	long parallel straight



These are not joints:
arms cannot be moved
for being positioned horizontally
coaxial

Functional configuration of instant device claims vs Landgrebe's



The Instance Device

1. The devices have different purposes and have been designed structurally different.
2. The preferred embodiment of the instance device has an aperture or hole (U). Landgrebe lacks it.
3. The surgical approach is different.
4. The four anchoring points are different.
5. The final position in the pelvis is different.



Landgrebe

1) The devices have different purposes

Instant device

Ideated primarily for prolapsed pelvic organs (bladder, uterus, intestine, (enterocele) to return them to their normal anatomical position. In some cases it also resolves urinary incontinence.

Landgrebe device

Ideated primarily for urinary incontinence. In some cases it can return **only the bladder** to its normal anatomical position.

2) The Instant device includes a central aperture or hole (U): Landgrebe lacks it.

Instant device

The function of the aperture is to surround the prolapsed uterus neck to return it to its normal anatomical position and then to prevent the prolapse from recurring.

Landgrebe device

This device offers no possibility of curing prolapse of the uterus.

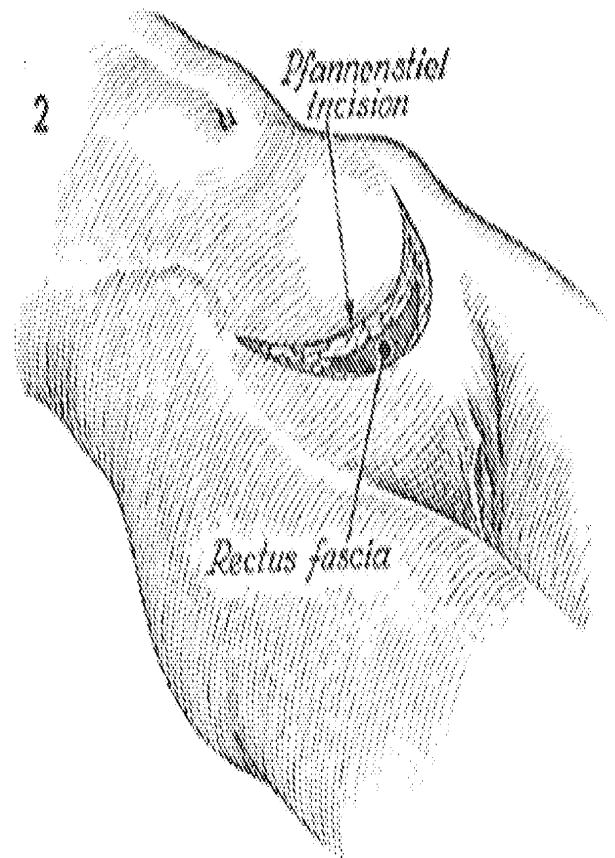
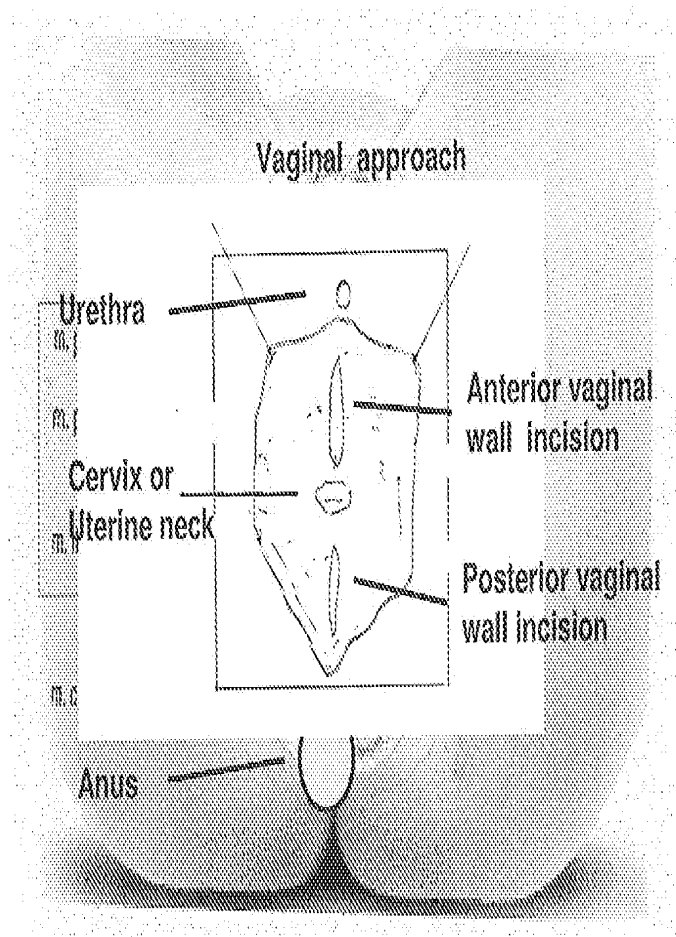
3) The surgical approach is different

Instant device

Ideated to be used in a vaginal surgical procedure.

Landgrebe device

Ideated to be used only in an abdominal surgery.



The Pfannenstiel incision is semicircular and is made slightly above the mons pubis for a length of about 12 cm. Care must be taken to ensure that hemostasis is complete prior to entering the peritoneal cavity. The rectus fascia is opened

4) The four anchoring points are different

Instant device

Vaginal surgery:

Front Arms to arcus tendineous levator
Ani

Rear Arms to the sacro-spinous ligament.
The result is that these arms lie to the rear,
deep in the pelvic floor.

Landgrebe device

Abdominal surgery:

Front Arms to ligamentum
pubicum superior

Rear Arms to the abdominal
musculus rectus
The result is that these arms rise
in front, toward the muscle of
anterior abdominal wall.

5) The final position in the pelvis is different

Instant device

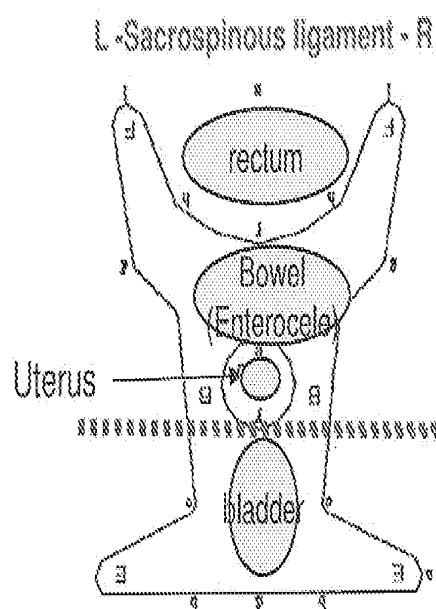
It is placed:

under the bladder,

in front of, around, behind the uterus neck,

under the intestine (enterocele),

in front of the rectum (final part of the Intestine situated in the pelvic cavity, not in the abdominal rectum muscle).



L - Tendinous arch of the levator ani- R

Landgrebe device

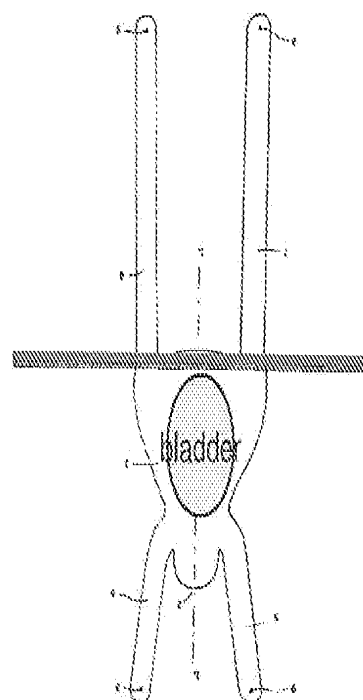
It is placed:

under the bladder.

Has no relation to the uterus, intestine, or rectal intestine

(the rear projections 7, 8 are fixed to the rectum muscle of the abdominal wall, and have no relationship to the rectal intestine in the pelvic cavity).

L - Musculus rectus abdominis- R



L - Ligamentum pubicum- R

5) The final position in the pelvis is different

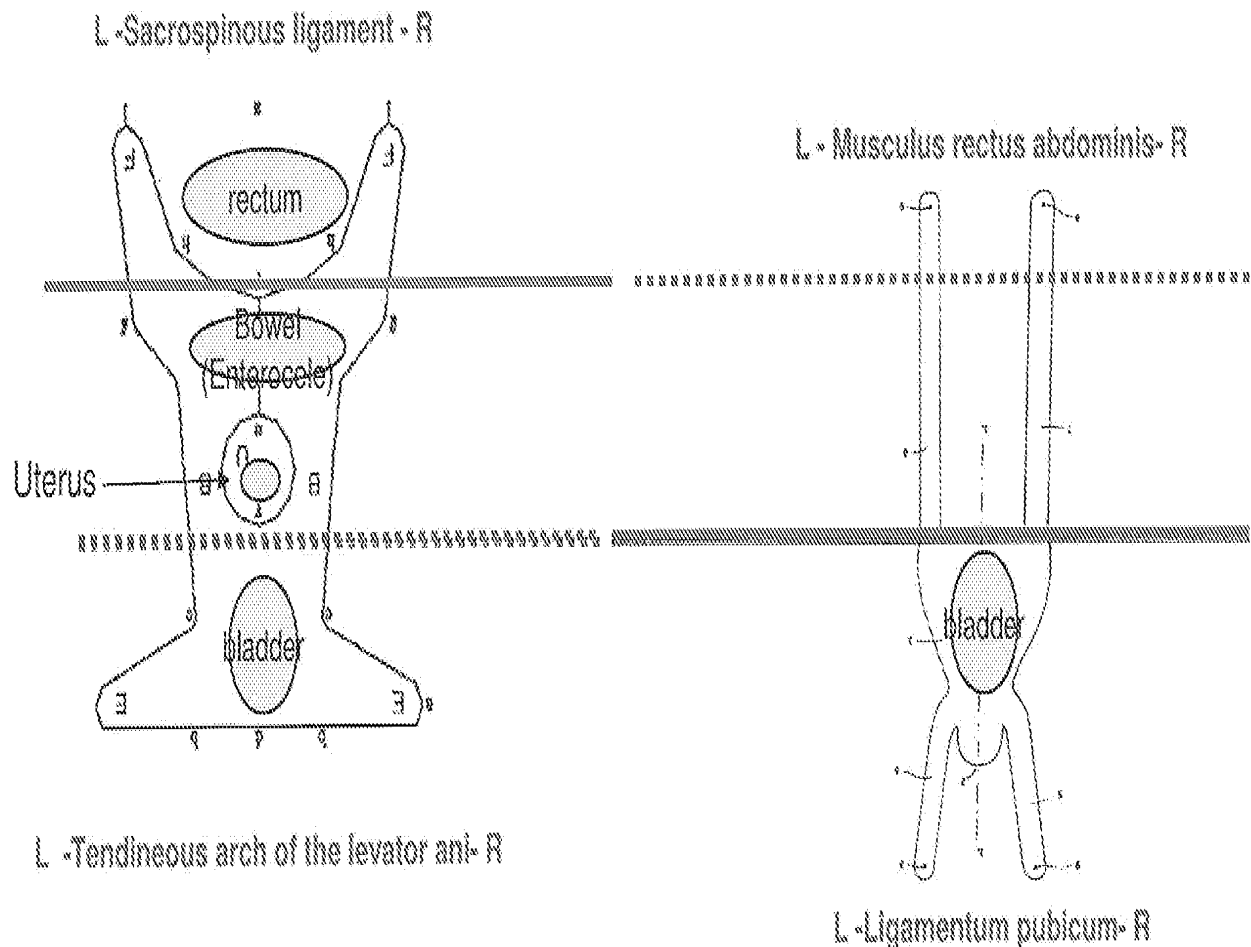
Instant device

Landgrebe device

Green line marks where the Landgrebe's device's support ends. Bladder only is sustained.

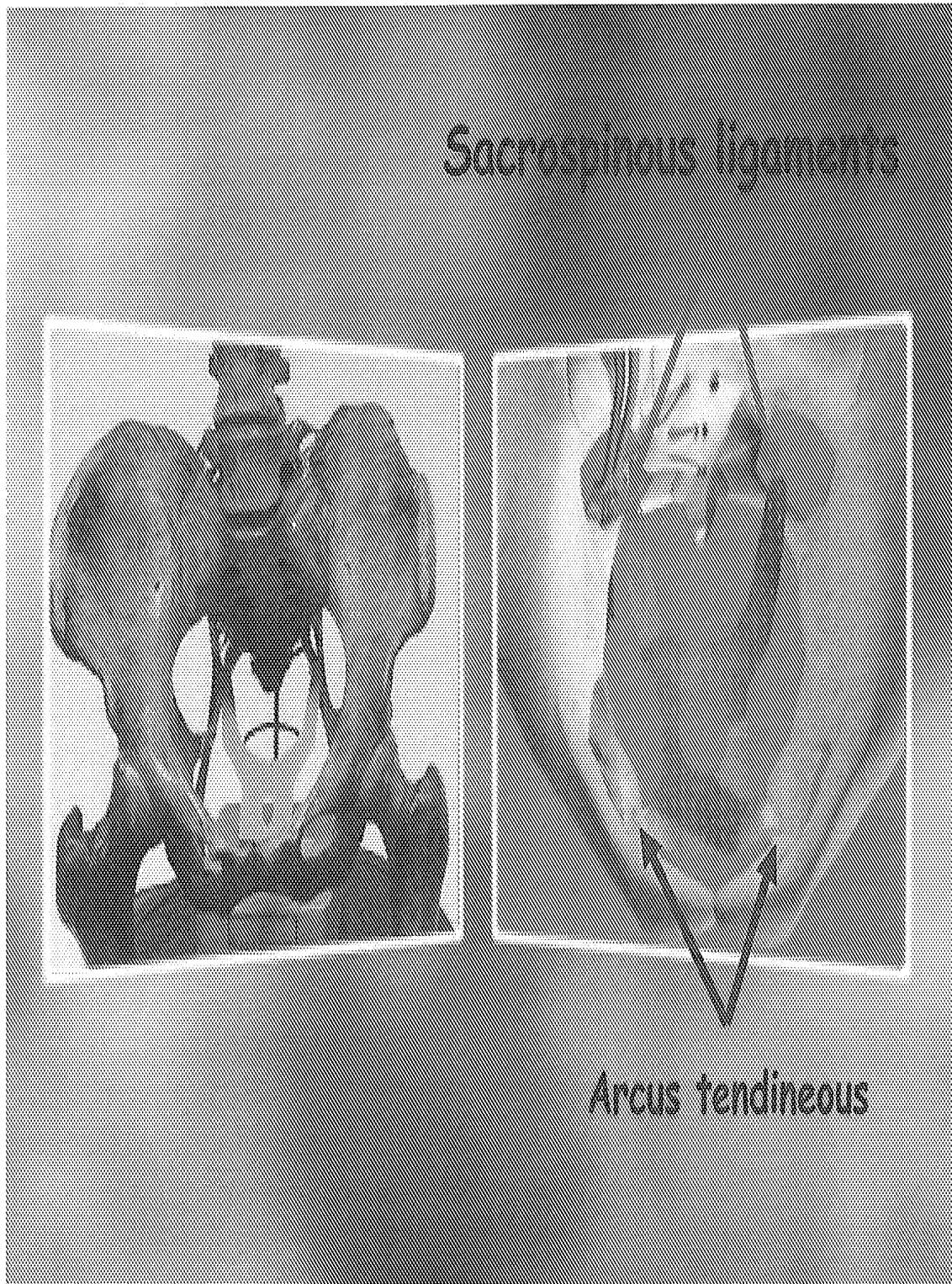
Brown line marks where the Instant device's support ends. Bladder, uterus and enterocele (small intestine) are sustained.

In both devices the 4 appendixes (projections) are only anchoring stay wires of the central parts.



Ultimate Position of the Mesh in the Pelvis

Frontal view



Normal Female Pelvic Floor

MR Sagittal View

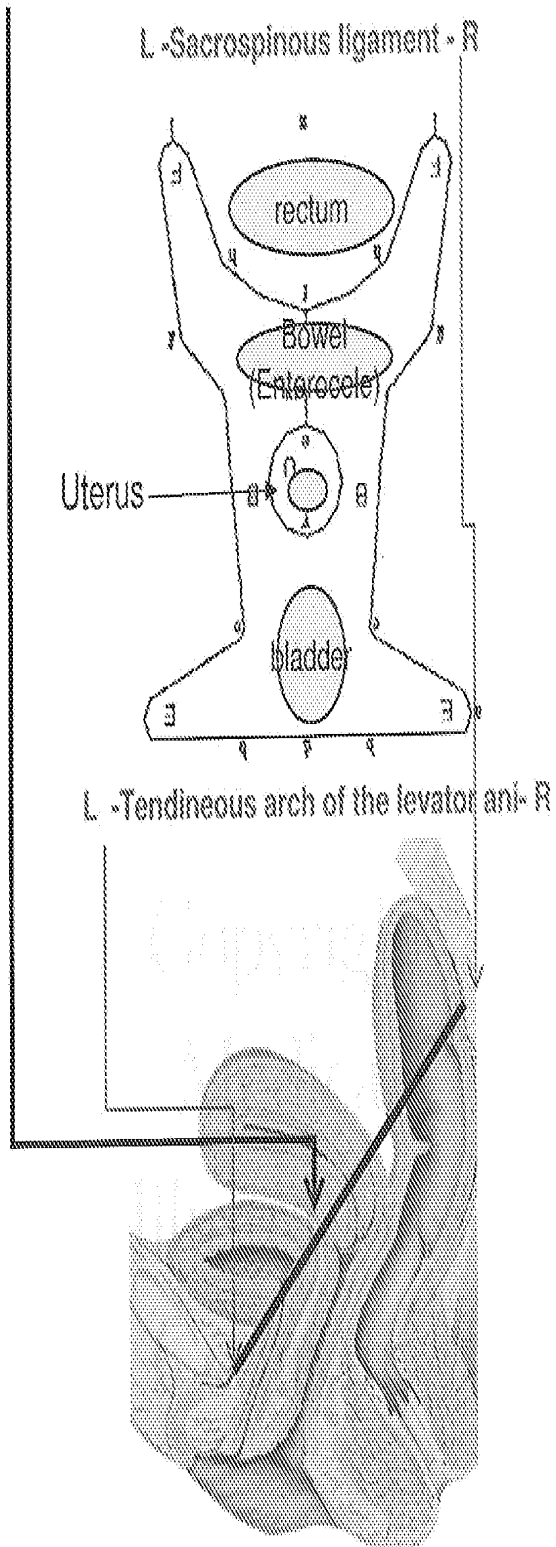


Red line from Trans Obturator Fascia to Sacrospinous Legament shows that mesh pelvic floor repair coincides with Levator Ani normal anatomy.

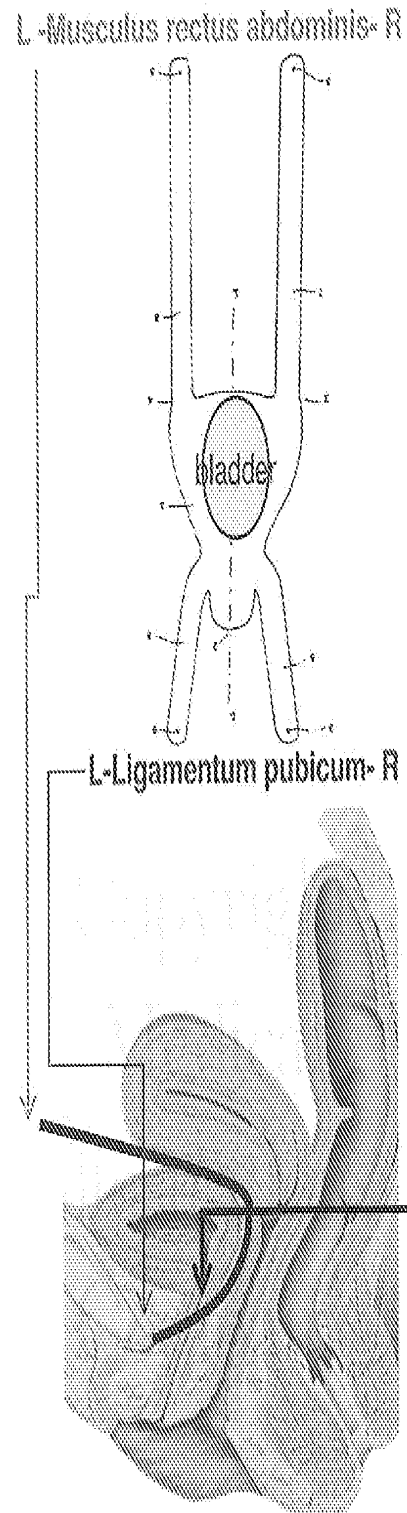
The mesh reconstitutes a new real Levator Any fascia: the anterior wings have the support function of the pubo-urethral and pubo-vesical ligaments. The part of the mesh encircling the cervix substitutes the function of the cardinal ligaments and the rear anchoring system to sacro-spinous that of the sacro uterine ligaments.

5) The final position in the pelvis is different

Instant device

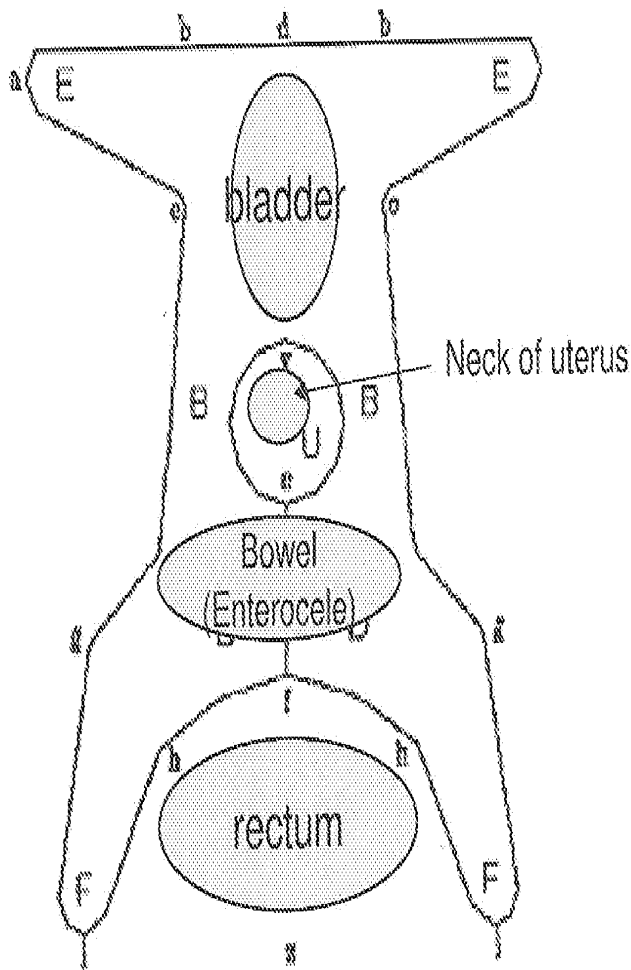


Landgrebe's device



The instant device function and implant

Tendineous arch of the levator ani



Sacrospinous ligament

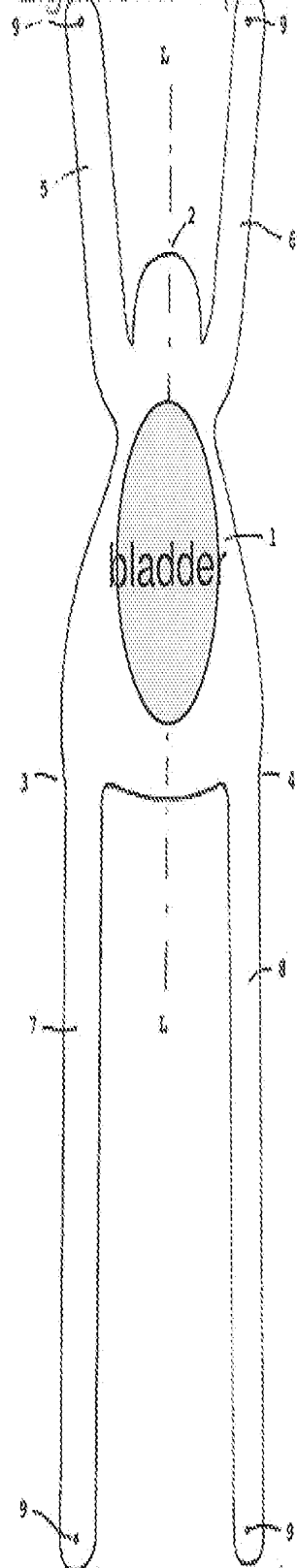
[0061] The present device is applied by surgery; during surgery, the habitual means of access is the vagina, with an incision extending from the front vaginal wall to the rear wall, excluding the neck of the uterus.

[0062] Through the front vaginal wall the tendinous arch of the levator ani is penetrated, which is opened bilaterally for about 2 cm, and on which the two arms E are fixed respectively on the right and on the left.

[0063] The two rear arms F are then passed by the sides of the neck of the uterus, one on the right and one on the left, and are laid until the central part B surrounds the neck of the uterus. The right and the left half of the rear portion of the device are rejoined in the centre with two stitches and the rear arms are fixed bilaterally to the sacrospinous ligament or to the iliococcygeal muscle. At the end of the operation the device, anchored by means of the four arms to the tendinous arch of the levator ani and to the sacrospinous ligament (or to the iliococcygeal muscle), is at the normal anatomical level of the levator ani muscle. Consequently, also the organs resting on it, the bladder at the front (cystocele), the neck of the uterus in the centre (hysterocele), the rectum at the rear (enterocele), are returned to their correct anatomical plane above said muscle.

Landgrebe's device function and implant

Ligamentum pubicum



The wide base 1 of the implant comes to rest between the bladder and vagina. It should be ensured that the position of the allo-

← See column 4 lines 29-31

The two first projections 5, 6 or rear (distal) retropubic bridges are passed by the urethra on both sides and fixed to the ligamentum pubicum superior behind the two pubic rami.

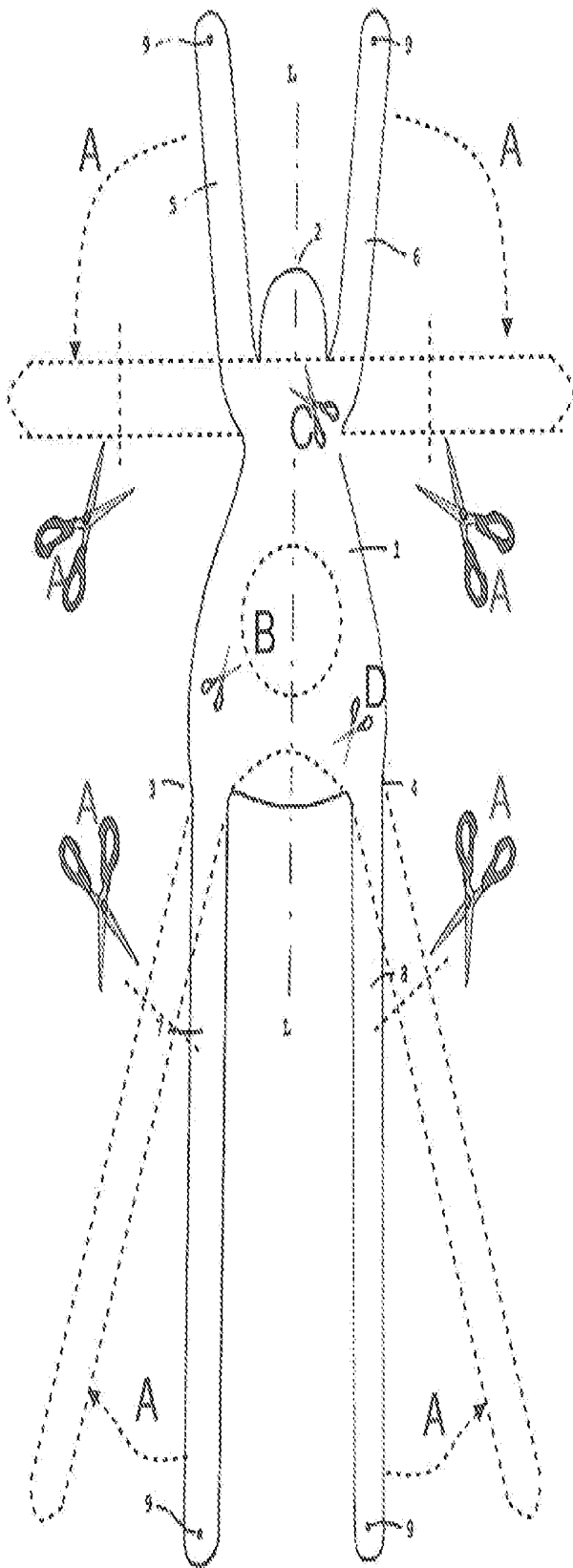
← See column 4 lines 35-41

The rear wall of the bladder from the bladder neck to the apex of the bladder rests with a large surface area on the implant. When the implant is introduced, it is to

The two second projections 7, 8 of the implant are pulled right and left through the musculus rectus and apposed crosswise over this.

← See column 4 lines 57-59

Musculus rectus abdominis



For the sake of argument, suppose that a surgeon attempts to use Langrebe's device and to anchor it in the pelvis at the same four anchoring points of the instant device.

Such proposed substitution would require all of the modifications listed below, and still would not be usable for the present invention.

Modifications A-D are described below, and shown in the adjacent Figure.

- A. arms and legs have to be shortened and moved wide apart (probably weakening their holding capability)
- B. A hole has to be made in the triangular base
- C. The projection (2) has to be cut away;
- D. Base of the triangle has to be modelled from convex to concave, to adapt it to the rectum.

These many modifications cannot be considered obvious.

In conclusion

- Even modifying Landgrebe's device by making a hole in its triangular base, would not result in the presently claimed device.
- Furthermore, making a hole in Landgrebe's device would allow or cause the bladder to fall downward, thus defeating the purpose for which Landgrebe device was designed for. Accordingly, Landgrebe would not teach to cut a hole in the central body.
- Landgrebe does not mention the possibility that its device could be used for correcting other than the bladder prolapse. So there is no suggestion that it could be for purposes other than the one for which it was designed.
- Thus the present invention is not a modification of Landgrebe but is a totally different device, used in a different way for a different purpose.